

Message Text

UNCLASSIFIED

PAGE 01 STATE 137846

15

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 EB-07 COME-00 /031 R

66618

DRAFTED BY DHEW/FDA/JRWEINROTH, MD

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW/OHI/MACODJING

EUR/CE:DANDERSON(INFO)

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R 122243Z JUN 75

FM SECSTATE WASHDC

TO AMEMBASSY BONN

UNCLAS STATE 137846

E.O. 11652: NA

TAGS: OGEN, ETRD, TBIO, GW

SUBJ: FDA ADVISORY-DEFECTIVE MEDICAL DEVICE

1. FDA ADVISES THAT THE METAL CONTROL VALVE DEVICE "BENDIX AIR/02 MIX PRECISION AIR/OXYGEN CONTROLLER, PART NO. APC-100-B1, SERIAL NUMBERS 101-577, MANUFACTURED BY THE BENDIX CORPORATION, INSTRUMENTS AND LIFE SUPPORT DIVISION, HICKORY GROVE ROAD, DAVENPORT, IOWA 52808 ARE BEING RECALLED FROM THE USER LEVEL.

2. THE REASON FOR THE RECALL IS THAT A LUBRICANT AND SEATING CEMENT USED IN THE DEVICES HAS MIGRATED INTO THE VALVE AREAS CAUSING THE VALVES TO UTICK AND NOT FUNCTION PROPERLY. THIS RESULTS IN AN IMPROPER AIR/02 MIXTURE WHICH MAY BE EITHER TOO HIGH OR TOO LOW FOR THE INDIVIDUAL PATIENT USER. THE FIRM DISCONTINUED PRODUCTION AND SALE OCTOBER 28, 1978 AND NOTIFIED ALL CUSTOMERS BY TWX NOVEMBER 15, 1974 REQUESTING ALL UNITS BE RETURNED FOR NEW PARTS, CLEANING AND REPAIR.

3. FOREIGN CONSIGNEE AS FOLLOWS:

DRAGERWERK AG

2400 LUBECK 1

MOISLINGER ALLEE 53-55

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PAGE 02 STATE 137846

WEST GERMANY SERIAL NO'S 150, 386

POUT IS REQUESTED TO CONTACT CONSIGNEE TO DETERMINE IF THEY HAVE
BEEN INFORMED OF RECALL AND ACTION TO BE TAKEN. ANY QUESTIONS THEY
MAY HAVE SHOULD BE REFERRED DIRECTLY TO MANUFACTURER.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 12 JUN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE137846
Document Source: CORE
Document Unique ID: 00
Drafter: FDA/JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750231-0442
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750655/aaaabyfb.tel
Line Count: 66
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: greeneet
Review Comment: n/a
Review Content Flags:
Review Date: 03 MAR 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <03 MAR 2003 by PhilliR0>; APPROVED <11 FEB 2004 by greeneet>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-DEFECTIVE MEDICAL DEVICE
TAGS: OGEN, ETRD, TBIO, GE, US
To: BONN
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006